

Package leaflet: Information for the patient
Apresoline® 25 mg Tablets
hydralazine hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. WHAT APRESOLINE 25 MG TABLETS ARE AND WHAT THEY ARE USED FOR

The name of your medicine is Apresoline 25 mg Tablets.

The active ingredient is hydralazine hydrochloride.

Hydralazine hydrochloride belongs to a group of medicines called antihypertensives.

Apresoline is used to treat adults with high blood pressure and heart failure.

It works by relaxing blood vessels and increasing the supply of blood and oxygen to the heart.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE APRESOLINE 25 MG TABLETS

Do not take Apresoline Tablets 25 mg :

- if you are **allergic to hydralazine** or any of the other ingredients in this medicine (listed in section 6) (allergic reactions include mild symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing);
- if you have or have ever had a condition called Systemic Lupus Erythematosus (SLE), an autoimmune condition which causes joint pain, skin rashes and fever;
- if you suffer from severe tachycardia or right sided heart failure due to increased pressure in the blood vessels of the lungs (cor pulmonale);
- if you suffer from thyrotoxicosis (an excess of thyroid hormones in the blood that can cause a fast heartbeat, sweating, trembling, anxiety, increased appetite, loss of weight and intolerance of heat);
- if you heart function impaired (myocardial insufficiency);
- if you have a condition known as porphyria.
- if you have a condition called dissecting aortic aneurysm.

Warnings and precautions

Take special care with Apresoline and Talk to your doctor or pharmacist before taking Apresoline tablets 25 mg

- if you have had a heart attack in the past three months;
- if you have coronary heart disease;
- if you have angina pectoris, which causes pain in the chest with exercise;
- if you have cerebrovascular disease (narrowing of the blood vessels in the brain);
- if you have been told you are a slow acetylator (this means that your body handles some medicines more slowly than other people);
- if you suffer from any serious liver or kidney problems;

- if you are experiencing fever, loss of appetite, weight loss, tiredness, general body pain, coughing which may produce tarry black deposits or blood, swelling of arms, hands, legs, feet and ankles, blood in urine while on treatment with Hydralazine. Talk to your doctor or nurse or pharmacist immediately.
- if you have blockage of one or more arteries that supply blood to the heart (coronary heart disease).
- If you have had blood tests before starting treatment.

Children and adolescents

Apresoline Tablets 25 mg Tablets are not recommended for use in children.

Other medicines and Apresoline tablets 25 mg

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is especially important that you tell your doctor if you are taking:

- medicines for high blood pressure, such as vasodilators (e.g. minoxidil or diazoxide);
- ACE inhibitors (e.g. enalapril, lisinopril, captopril);
- beta-blockers (e.g. propranolol);
- calcium antagonists (e.g. nifedipine or diltiazem);
- medicines for water retention (e.g. diuretics);
- medicines for problems such as depression, including monoamine oxidase inhibitors (MAOIs) (e.g. moclobemide, phenelzine, isocarboxazid, tranylcypromine);
- tricyclic antidepressants (e.g. amitriptyline, clomipramine) or tranquillisers (e.g. diazepam);
- medicines to control pain and inflammation (a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs));
- corticosteroids (e.g. prednisolone or prednisone);
- medicines to control psychoses;
- a specific group of medicines known as nitrates, used to control blood pressure;
- oestrogens (a group of female sex hormones used in contraception and in treating the menopause).

If you are going to have a **general anaesthetic**, you should tell the **doctor or dentist** in charge that you are taking Apresoline 25 mg Tablets .

Apresoline tablets 25 mg with food and drink and alcohol

It is advisable not to drink alcohol whilst taking Apresoline as it may affect you more than usual. Taking Apresoline with food may decrease the amount of the medicine in your system, therefore, take it before food.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

You can drive while taking Apresoline but do not drive until you know how the tablets affect you. They may make you feel dizzy or impair your reactions. If they affect you in this way, **do not** drive or operate any machinery.

Apresoline Tablets 25mg contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE APRESOLINE 25 MG TABLETS

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults

High blood pressure: The usual starting dose is one tablet (25 mg) taken twice a day. This may be increased up to 8 tablets a day (maximum of 200mg) by your doctor.

Heart failure: Treatment should be started in hospital, at a dose of 25 mg three or four times a day. 50 mg to 75mg four times a day is often given as a long-term dose. Your doctor will adjust the dose to suit you.

Use in children

Apresoline Tablets 25 mg is **not recommended** for use in children.

The tablets should be taken with a drink of water.

If you take more Apresoline Tablets 25 mg than you should

Symptoms of overdose include a faster or irregular heartbeat, low blood pressure, feeling sick, dizziness, and sweating. Chest pain, headache, vomiting, losing consciousness shaking, fits, decreased urine output and feeling cold are also possible symptoms. If you take more Apresoline **Tablets 25 mg** than you should, contact your doctor or go to your nearest hospital emergency department immediately. Take the container and any remaining tablets with you.

If you forget to take Apresoline Tablets 25 mg

If you forget to take a dose, just take the next dose at the usual time, **DO NOT** take a double dose to make up for a forgotten dose.

If you stop taking Apresoline

Ask your doctor before stopping treatment with Apresoline, as treatment should be stopped gradually over several days.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

STOP taking the medicine and seek immediate medical advice if you notice the following:

- Fever, loss of appetite, weight loss, coughing which may produce dark tarry black deposits or blood, swelling of arms, hands, legs, feet and ankles, blood in urine.
- SLE-type syndrome, which can cause symptoms such as joint pain, fever, change in blood count and skin rash;
- Allergic reactions including itching, skin rash, inflammation of the walls of small blood vessels and difficulty in breathing;
- Yellowing of the skin and whites of the eyes, which may indicate problems with the liver such as jaundice and hepatitis;
- Kidney failure (e.g. changes in urine, swelling of legs, ankles or feet, shortness of breath, tiredness and nausea).

Other side effects may include:

Very common (may affect more than 1 in 10 people)

- abnormal heartbeat (palpitations);
- an unusually fast heartbeat;
- headaches.

Common (may affect up to 1 in 10 people)

- chest pains;
- swelling and/or pain in joints, muscle pain;
- low blood pressure;
- feeling sick and being sick, particularly at the beginning of the treatment or after an increase in dose;
- diarrhoea;
- flushing.

Rare (may affect up to 1 in 1,000 people)

- heart failure, swelling;
- increased levels of a substance called creatinine in the blood;
- breathlessness, breathing difficulties or pain when breathing;
- liver enlargement;
- skin rash;
- blood in the urine which may be associated with a disease of the kidneys;
- presence of protein in the urine;
- inflammation or the abnormal functioning of the liver;
- watering or sore itchy eyes (conjunctivitis);
- a reduction in the number of platelets in the blood which can cause unexplained bruising or rashes;
- a reduction in red blood cells, which can make you feel tired or breathless with physical exertion;
- a reduction in certain white blood cells which may make you more susceptible to infections;
- fever;
- anxiety;
- restlessness;
- blocked or stuffy nose;
- loss of appetite;
- weight loss;
- dizziness;
- generally feeling unwell.

Isolated cases

- a change in the amount of urine produced;
- a restriction of movement in part of the intestine;
- a deficiency of certain white blood cells which can result in fever and ulceration of the mouth and throat;
- an increased number of white blood cells;
- enlargement of the spleen and liver;
- a reduction in the number of red and white blood cells and platelets in the blood;
- depression;
- seeing or hearing things which are not really there (hallucinations);
- inflammation of the nerves which may cause weakness or numbness especially in your fingers and toes;
- tingling (pins and needles) in your hands or feet;
- disease of the lymph nodes;
- enlarged eye balls;
- the inability to completely or partially empty the bladder;
- opposite effect of medical treatment (episodes of high blood pressure);
- an increase in other kinds of white blood cells.

Not known: frequency cannot be estimated from the available data

- Involuntary shaking or movement (tremors)
- Inflammation of veins and arteries (Systemic vasculitis) which may lead to a rare medical syndrome involving bleeding in the lungs and kidney damage (Pulmonary renal syndrome).

If you feel very tired, experience unexpected bruising or bleeding, or more infections (e.g. colds and sore throats) than usual please tell your doctor. Your doctor may decide to conduct tests on your blood periodically as a result of these symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor or, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE APRESOLINE 25 MG TABLETS

Keep this medicine out of the sight and reach of children.

Store in the original package in order to protect from moisture. Protect from heat. Store below 30°C.

Do not use this medicine after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Apresoline 25 mg Tablets contains

Each tablet contains 25 mg of the active substance hydralazine hydrochloride. The other ingredients are: maize starch, microcrystalline cellulose, povidone, colloidal silica anhydrous, magnesium stearate, copovidone, hypromellose, titanium dioxide, talcum powder, sucrose, polyethylene glycol, cellulose microcrystalline, dispersed yellow.

What Apresoline 25 mg Tablets looks like and contents of the pack

Apresoline 25 mg Tablets are pale yellow, round, biconvex sugar-coated tablets.

Apresoline is available in packs of 56, 84 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Amdipharm UK Limited,
Dashwood House,
69 Old Broad Street,
London, EC2M 1QS,
United Kingdom

Manufacturers responsible for Batch Release:

Rottendorf Pharma GmbH,
Ostenfelder Straße 51-61,
59320 Ennigerloh,
Germany

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